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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)	
1001.2256101	

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Typed or printed name THU H. LE-TO

Application Number	Filed
10/083,707	FEBRUARY 26, 2002
First Named Inventor	
GREGORY G. BRUCKER	
Art Unit	**Examiner**
3773	MELANIE RUANO TYSON

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. ☑

This request is being filed with a notice of appeal. ☑

The review is requested for the reason(s) stated on the attached sheet(s). ☑
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☑ attorney or agent of record.
Registration number 41,376

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34

Signature

J. SCOT WICKHEM
Typed or printed name

612.677.9050
Telephone number

10-15-08
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	GREGORY G. BRUCKER et al.	Confirmation No.:	1518
Serial No.:	10/083,707	Examiner:	Melanie RuanoTyson
Filing Date:	FEBRUARY 26, 2002	Group Art Unit:	3773
Docket No.:	1001.2256101	Customer No.:	28075
Title:	BIFURCATED STENT AND DELIVERY SYSTEM		

PRE-APPEAL CONFERENCE BRIEF

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Thu H. Le-To	OCTOBER 15, 2008
	Date

Dear Sir:

Applicants have carefully reviewed the Final Office Action dated July 15, 2008 and the Advisory Action dated October 6, 2008. Currently, claims 17, 19, and 39-62 are pending in the application, all of which have been finally rejected. Applicants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal.

On page 2 of the Final Office Action, claims 47-56 and 62 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner asserted that, at the time the application was filed, the applicant failed to disclose, "after expansion of the bulge portion a portion of the bulge portion is positioned within the circumferential plane". Applicant must respectfully disagree. Additionally, in the Advisory Action, the Examiner asserted that that the applicant disclosed that the entire bulge portion extends radially through the side opening outside the circumferential plane after expansion. Applicant respectfully asserts that in order for a portion of the bulge portion to extend radially through the side opening outside the circumferential plane, at least a portion of the bulge portion is positioned within the circumferential plane.

Applicant notes that "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.' ... to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed." (See MPEP § 2163.02). Applicant respectfully asserts that the application as filed clearly conveys to a person of ordinary skill in the art that Applicant possessed the above-noted limitation. For example, page 11, lines 11-15, recites "However, in at least one embodiment, balloon 30 also includes a unique geometry which in the expanded configuration, comprises a bulge region 34 that would effectively push against members 24 to push the members 24 outward from the stent body 12 to expand the members 24 to expand outward to form the scaffold 14". In this configuration, a person of ordinary skill would clearly understand that a portion of the bulge portion would be positioned within the circumferential plane. Therefore, claims 47-56 and 62 are believed to comply with the written description requirement of § 112, first paragraph.

On page 3 of the Final Office Action, claims 17, 19, 39, 40, 46, 57, 58, and 61 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lam (US 5,607,444) in view of Vardi et al. (US 6,325,826). After careful review, Applicants must respectfully traverse the rejection. Claim 17 recites, in part, "only a single catheter, the single catheter having only a single balloon", "the stent body being expandable from an unexpanded condition to an expanded condition by expansion of the single balloon extending within the stent wall from at least a proximal end to at least a distal end of the stent body", or "in the expanded condition a portion of the plurality of movable members being extended radially outward from the stent wall to form a scaffold, the scaffold defining a side opening in the stent wall". Nowhere does the combination of Lam and Vardi et al. appear to teach or suggest these limitations.

Instead, Lam appears to teach an ostial stent having a tubular body and a deformable flaring portion. The deformable flaring portion, however, appears to be disposed at an end of the stent, in contrast to claim 1, which claims "the scaffold defining a side opening in the stent wall". Lam appears to further teach that the deformation of the flaring portion (at the end of the stent) is accomplished by expanding a balloon or a series of balloons that extend out the end of the stent.

However, nothing in Lam appears to teach or suggest a technique for expanding a side opening of a stent wall with a single balloon. Additionally, the Examiner relies on Vardi et al. as teaching the scaffold defining a side opening in the stent wall, such that a portion of the movable members expand towards a proximal end of the stent body and a portion of the movable members expand towards a distal end of the stent body. However, nothing in Vardi et al. appears to teach or suggest expanding the scaffold defining a side opening in the stent wall with a single balloon. As such, neither reference appears to teach how to expand moveable members at a side opening of the stent with only a single balloon.

In combining the teachings of Vardi et al. with Lam in an attempt to show the claimed invention is obvious, the Examiner states "It is well known within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device to yield predictable results". Applicant respectfully asserts that nothing in Lam or Vardi et al. appears to teach or suggest a technique for expanding scaffold defining a side opening in the stent wall with a single balloon. In the Final Office Action, the Examiner stated:

> It is well known within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the movable members on a side wall, such that the radially expand to from a scaffold defining a side opening in the stent wall as taught by Vardi. Do so would provide the stent the ability to be positioned across the bifurcation with the side opening positioned over the bifurcation point.

Additionally, in the Advisory Action, the Examiner asserts that the noted known technique refers to the technique of providing expandable members on a side opening, as opposed to the ends, of a stent. However, merely providing expandable members on a side opening of a stent does not teach or suggest how to open expandable members on a side opening with a single balloon, as neither reference appears to teach or suggest such a technique.

Applicant notes that"[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious"...The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit." (See MPEP § 2141). Further, the Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006), "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some

articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." Emphasis added; see page 14 of the April 30, 2007 decision. The Court further stated, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." See page 14 of the April 30, 2007 decision. As such, the Examiner is required to provide clearly articulated reasons why the individual elements would be obvious to combine. As discussed previously, there appears to be no known technique taught by the cited references that can be applied to the other cited reference to arrive at the claimed invention and, thus, there is clearly no *prima facie* case of obviousness. Therefore, for at least these reasons, claim 17 is patentable over Lam and Vardi et al. and withdrawal of the rejection is respectfully requested. For similar reasons and others, claims 19, 39, 40, 46, 57, 58, and 61 are patentable over Lam and Vardi et al.

On page 4 of the Final Office Action, claims 41-45, 59 and 60 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lam (US 5,607,444) in view of Vardi et al. (US 6,325,826), and further in view of Crocker et al. (US 5,843,116). For reasons discussed above and other reasons, claims 41-45, 59, and 60 are patentable over the cited references.

On page 5 of the Final Office Action, claims 47-56 and 62 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Vardi et al. (US 6,325,826) in view of Marotta et al. (US 6,261,305). After careful review, Applicants must respectfully traverse the rejection. Claim 47 recites, in part, "the balloon arrangement including an elongate body portion and a bulge portion configured to protrude radially outward from the body portion when expanded, the bulge portion being positioned at a location between a proximal end and a distal end of the body region and positioned at a predetermined circumferential location around a circumference of the body region, the bulge portion extending around less than an entire circumference of the body region" and "the movable members being expandable from an unexpanded position in which the movable members are retained substantially within the circumferential plane to an expanded position extending radially outwardly from the stent wall by expansion of the bulge portion of the balloon arrangement to define a side opening in the stent".

In the Final Office Action, the Examiner appears to rely on Marotta et al. as teaching or suggesting "the balloon arrangement including an elongate body portion and a bulge portion configured to protrude radially outward from the body portion when expanded". However,

Marotta et al. appears to teach an endovascular prosthesis, not a stent, wherein a leaf portion moves away from the tubular plane of the body 105 as the body is flexed upon navigation into a secondary artery. However, nothing in Marotta et al. appears to teach or suggest a balloon arrangement including a bulge portion configured to protrude radially outward from the body portion when expanded to expand the movable members of the bifurcated stent to a position extending radially outwardly from the stent wall to define a side opening in the stent. In fact, Marotta et al. appears to teach away from using the described balloon with a stent. Marotta et al. states "The present endovascular prosthesis is not a stent, per se, since design requirement (ii) need not be met – i.e., the aim of the present endovascular prosthesis is not to maintain patency of blocked body passageway. Rather, the present endovascular prosthesis comprises one or more expandable elements for the purposes of securing the prosthesis in the correct position." (Column 6, lines 61-67). MPEP § 2141.03 states "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP § 2146 states "It is improper to combine references where the references teach away from their combination". Thus, Applicant respectfully asserts that Marotta et al. teaches away from using a stent and, as such, the combination of Vardi et al. and Marotta et al. is clear error. Therefore, for at least these reasons, claim 47 is patentable over Vardi et al and Marotta et al. For similar reasons and others, claims 48-56 and 62 are patentable over Vardi et al and Marotta et al. and withdrawal of the rejection is respectfully requested.

Reconsideration and withdrawal of the rejection are respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

GREGORY G. BRUCKER et al.

By their Attorney,

Date: 10-15-08

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